

9312 'GO JUN 20 P3:42

TheraLife Inc.

101 First Street, Suite 343

Los Altos, CA 94022

Tel:: (650) 917-1989

Fax: (650) 917-1434

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C Street SW Washington, DC 20204

June 03, 2000

Notification Letter for Statement on Dietary Supplement

Dear FDA officers:

This notification is being filed on behalf of Theralife, Inc., which is the manufacturer of the product, which bears the statements identified in the notification. This notification is being made pursuant to Code of Federal Regulations, Volume 21, Part 101.93 to notify you that we have included a statement on the label or in the labeling of one of our products. The following are the information required in this notification letter:

1. Statement of Purpose:

This is a letter to provide notification of a statement of nutritional support, including the exact wording that appears on the label and labeling for a dietary supplement.

2. Vendor Information:

Name, address, telephone and fax numbers of the manufacturer and distributor for mailing and other communication purposes are as follows:

101 First Street, Suite 343, Los Altos, CA 94022; Phone: (650) 917- 1989, Fax: (650) 917-1434, www.theralife.com

LE 1558971171

Theralife, Inc.

101 First Street, Suite 343, Los Altos, CA 94022

Tel:: (650) 917-1989 Fax: (650) 917-1434

The above address is also used for consumer inquiries.

3. Product Identification:

The trade name of the product:

Theralife® Wrist

The common and usual name of the product:

None.

A label copy showing all information displayed and provided to consumers is attached.

4. The text of the Structure/Function Statement:

Wrist reliever

5. Ingredient Statement

This product is a Vitamin/Mineral/Herb product with a proprietary blend of herbs. The following is a complete list of dietary ingredients:

Vitamin C (Ascorbic Acid)
Vitamin B-6
Vitamin E
Beta-Carotene
Niacin
Quercetin
Riboflavin
Zinc
Selenium
Proprietary Herbal Blend

			· ·
Common Name	Chinese name	Latin Name	Part of Plant
Astragalus	Huangqi	Astragalus membranaceus	Root
Ledbouriella	Fangfeng	(Fisch)Bge Saposhnikovia divaricata (Turcz)	Root
Cinnamomum	Guizi	Cinnamomum cassia Blume	Bark
Dangqui	Dangqui	Angelica sinensis (Oliv) Diels	Root
Corydalis	Yanhusuo	Corydalis yanhusud W.T.Wang	o Root

6. Intended Use:

This product is intended to be used by adult over the age of 18.

Suggested use: Adults take 2 capsules with water two to three times a day. Take 3 capsules with 3 capsules of Theralife Enhancer Formula three times daily for maximum results as needed.

Warning: Store at room temperature and avoid excessive heat. Use for adults only and not for pregnant or nursing women. Bottle cap should be foil sealed.

7. Statement of Affirmation:

We, as a manufacturer and distributor of the above mentioned product, affirm that we have substantiation that the structure/function statement (as shown in No. 4 above) made under 403(6)(r) of the Federal Food, Drug and Cosmetic Act is truthful, not misleading, and scientifically valid and that the product does not present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the label or labeling.

8. Disclaimer:

The disclaimer reads:

The statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Should there be any question or comment, please contact the Vendor through the information in No. 2 above.

Sincerely,

President and Chief Executive Officer

SI

Suggested Use: Adults take 2 capsule with water two to three times a day. Take 3 capsules with 3 capsules of Enhancer Formula three times daily for maximum results as needed.

Proprietary Herbal Blend Patent pending

24 Capsules
Trial Size

Vitamin/Mineral/10 farning: Store at room temperature and avoid excessive Supplement Facts Se Amount Per 2 Capsules Ascorbic Acid 200 ms Vitamin B-6 67 mg Vitamin E 34 IU Beta-Carotene 5906 ff Niacin 17 mg Quercetin 17 mg Vitamin B-5 8.4 mg Riboflavin 8.4 mg Thiamin 8.4 mg Zinc 5 mg Selenium 68 mcg Proprietary Herbal Big Astragalus, Leibouriell Cinnamomuni, Dailball Corvdalis Yanhusue Other ingredients: mag * Daily value not establis

TheraLife® Wrist

Reliever

TheraLife

ife Inc. | 94022 |

62204 80011

